

REMARKS

The Amendments

The amendments are made to address the claim objections and other obvious informalities. Claim 1 is further amended in accordance with the disclosure at, e.g., page 8, second full paragraph, and the paragraphs bridging pages 99-100 and 100-101.

Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which has been canceled by any of the above amendments.

The Claim Objections

The objections to claim 17 are rendered moot by cancellation of the claim.

The objections to claims 1 and 21 are rendered moot by the claim amendments.

The Rejection under 35 U.S.C. §112, first paragraph, for Lack of Written Description

The rejection of claims 1, 3, 5, 17, 21 and 23-25 under 35 U.S.C. §112, first paragraph, for lack of written description, is respectfully traversed.

The claims are rejected based on the allegation that applicants' disclosure fails to provide adequate written description of the term "*hedgehog* antibody." The invention of the elected claims herein lies in the combination of an initial diagnostic step of determining whether a tissue having unwanted cell proliferation overexpresses a *gli-1* gene and the recognition that a hedgehog antibody is particularly useful to decrease such unwanted cell proliferation in the tissue. The invention of these elected claims is not primarily based on identifying specific hedgehog antibodies (although, as previously pointed out and further discussed below, the specification also does provide guidance on assays to identify specific hedgehog antibodies).

The claim language at issue here is, in essence, original claim language and also has literal support in the specification. Thus, the question here is not whether applicants were in possession of the invention. Clearly, the disclosure literally describes the terms of the claims subject to rejection here. In this situation, there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed; see, e.g., In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976), and the written description guidelines in MPEP §2163. The situations where lack of written description is

found for original claim language or claims have literal support in the disclosure are described in MPEP §2163, part I.A. The instant facts do not fall under such situations because, as evidenced for example by Baxter (U.S. Patent No. 6,545,005), hedgehog antagonists were known in the art. That not all possible hedgehog antagonists may yet be known in the art, does not change this conclusion. To draw a simple analogy, many patent claims contain the word "solvent." The fact that other solvents may and will be discovered in the future does not support that claims having such term lack adequate written description. In this illustration, the invention does not rely on the novelty of solvents to support the invention. The principle is the same in the instant case. The novelty of applicants' invention of the elected claims lies in the combination of an initial diagnostic step of determining whether a tissue having unwanted cell proliferation overexpresses a *gli-1* gene and the recognition that hedgehog antibodies are particularly useful to decrease unwanted cell proliferation in such a tissue which overexpresses a *gli-1* gene. The invention does not rely on the novelty of hedgehog antibodies, in general, since clearly such were already known at the time of applicants' invention.

For this reason, at least, it is urged that the claimed invention has adequate written description from the original claims and the PTO has not met provided evidence to overcome the "strong presumption" of adequate written description in such case.

The Vas-Cath v. Mahurkar decision cited in the Office Action is distinguished on the facts, because it does not relate to a situation where the claim language in dispute was contained in the original claims.

Although it is not believed necessary in view of the above arguments, applicants also submit that the description, to one of ordinary skill in the art, provides an adequate description of the full scope of the term hedgehog antibodies useful herein.

It is alleged in the Office Action that the disclosure fails to identify, with particularity, any conserved structure or function of the intended antibodies. However, the claims do recite "hedgehog antibodies" and the specification does provide good guidance of the nature of the hedgehog genes and proteins to which the hedgehog antibodies apply. See, e.g., pages 1-7 of the specification. Based on this knowledge, one of ordinary skill in the art would be provided sufficient guidance as to the nature of the antibodies thereto. The disclosure in the paragraph bridging pages 17-18 also provides guidance as to the relation between the antibodies and the known hedgehog proteins and genes. Additional guidance is provided by the disclosure at page 88. This provides examples of the type of relation to particular genes that will give an

antibody the necessary antagonist activity for the invention. The disclosure here also provides guidance (with patent references) to one of ordinary skill in the art how to construct and screen libraries for antibodies having suitable anti-proliferative activity.

In addition to the guidance provided in the disclosure, the knowledge available to those of ordinary skill in the art also supports that the "hedgehog antibody" term would be of recognized meaning. The knowledge in the art of hedgehog genes and proteins and the knowledge in the art of at least one known hedgehog antagonist antibody is such that one of ordinary skill in the art would have a reasonable knowledge of the epitopes applicable to provide suitable antibodies, particularly using known screening methods.

For all of the above reasons, it is urged that the instant elected claims have sufficient written description in the specification and the rejection under 35 U.S.C. §112, first paragraph, should be withdrawn.

The Provisional Obviousness-type Double Patenting Rejection

The provisional obviousness-type double patenting rejection of claims 1, 3, 5, 17, 21 and 23-25 is formally traversed. Positive action to overcome this rejection, such as by filing a terminal disclaimer, would be premature at this point because both applications are still pending and are subject to rejections. Thus, the claims may be amended in such a way that the provisional rejection in no longer applicable.

It is submitted that the application is in condition for allowance. But the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

Respectfully submitted,

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